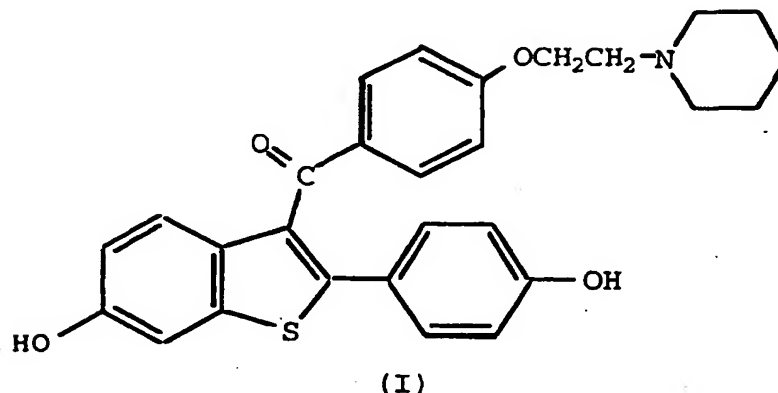


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We claim:

1. A method for preventing breast cancer in a human which comprises administering to said human for a sufficient term an effective dose of a compound of the formula



10

or a pharmaceutically acceptable salt or solvate thereof.

2. The method of Claim 1 wherein said effective dose is between about 30 mg to about 200 mg/day.

3. The method of Claim 1 wherein said effective dose is between about 50 mg to about 150 mg/day.

4. The method of Claim 1 wherein said effective dose is between about 60 mg to about 120 mg/day.

25

5. The method of Claim 1 wherein said effective dosage is about 60 mg/day.

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6. The method of Claim 1 wherein said term is at least six months.

5 7. The method of Claim 1 wherein said term is at least one year.

8. The method of Claim 1 wherein said term is at least two years.

10 9. The method of Claim 1 wherein said term is chronic.

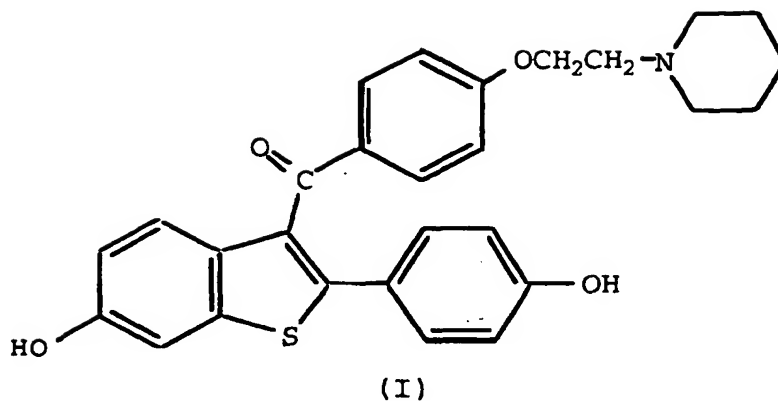
15 10. The method of Claim 1 wherein said compound is the hydrochloride salt thereof.

11. The method of Claim 1 wherein said human is a post-menopausal female, at no particular risk of developing breast cancer.

20 12. The method of Claim 1 where said breast cancer is *de novo*.

25 13. The method of Claim 1 wherein said human is a post-menopausal female.

30 14. A method for preventing breast cancer in a post-menopausal human female which comprises administering to said post-menopausal human female for a sufficient term an effective dose of a compound of the formula



or a pharmaceutically acceptable salt or solvate thereof.

15. The method of Claim 14 wherein said effective dose is between about 30 mg to about 200 mg/day.

16. The method of Claim 14 wherein said effective dose is between about 50 mg to about 150 mg/day.

17. The method of Claim 14 wherein said effective dose is between about 60 mg to about 120 mg/day.

18. The method of Claim 14 wherein said effective dosage is about 60 mg/day.

19. The method of Claim 14 wherein said term is at least six months.

20. The method of Claim 14 wherein said term is at least one year.

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21. The method of Claim 14 wherein said term is at least two years.

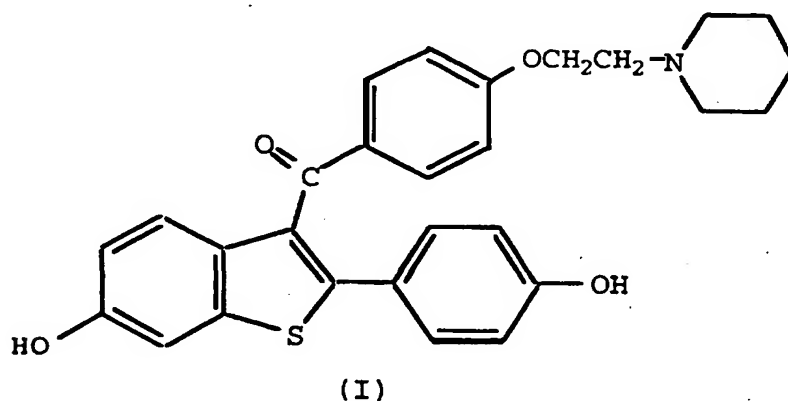
5 22. The method of Claim 14 wherein said term is chronic.

23. The method of Claim 14 wherein said compound is the hydrochloride salt thereof.

10 24. The method of Claim 14 wherein said post-menopausal female is at no particular risk of developing breast cancer.

15 25. The method of Claim 14 where said breast cancer is *de novo*.

26. A method for preventing breast cancer comprising administering to a human for a sufficient term an effective dose of a compound of formula I



20 or a pharmaceutically acceptable salt or solvate thereof, said human being at no particular risk of developing breast cancer.

25

27. The method of Claim 26 wherein said effective dose is between about 30 mg to about 200 mg/day.

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28. The method of Claim 26 wherein said effective dose is between about 50 mg to about 150 mg/day.

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29. The method of Claim 26 wherein said effective dose is between about 60 mg to about 120 mg/day.

10

30. The method of Claim 26 wherein said effective dosage is about 60 mg/day.

31. The method of Claim 26 wherein said term is at least six months.

15

32. The method of Claim 26 wherein said term is at least one year.

33. The method of Claim 26 wherein said term is at least two years.

20

34. The method of Claim 26 wherein said term is chronic.

25

35. The method of Claim 26 wherein said compound is the hydrochloride salt thereof.

36. The method of Claim 26 wherein said human is a post-menopausal female.

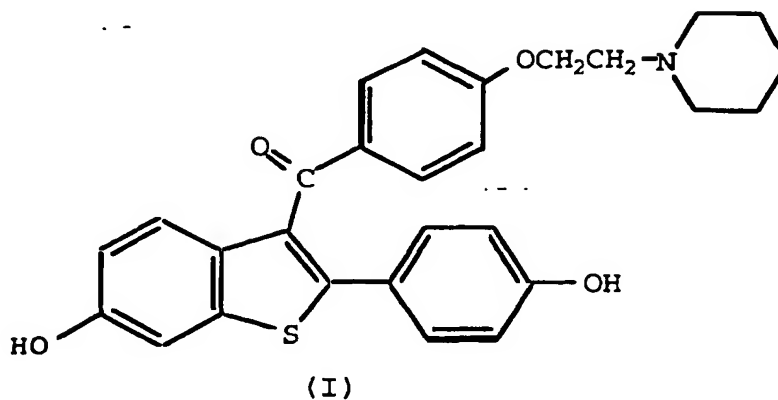
30

37. An article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said packaging material comprises a label which indicates said pharmaceutical agent may be administered, for a sufficient term at an effective dose, for preventing

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breast cancer in a human and wherein said pharmaceutical agent is a compound of formula I



5                    or a pharmaceutically acceptable salt or solvate thereof.

10                    38. An article of manufacture of Claim 36 wherein said label indicates an effective dose of the compound of formula I is between about 30 mg to about 200 mg/day.

15                    39. An article of manufacture of Claim 36 wherein said label indicates an effective dose of the compound of formula I is between about 50 mg to about 150 mg/day.

20                    40. An article of manufacture of Claim 36 wherein said label indicates an effective dose of the compound of formula I is between about 60 mg to about 120 mg/day.

25                    41. An article of manufacture of Claim 36 wherein said label indicates an effective dosage of the compound of formula I is about 60 mg/day.

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42. An article of manufacture of Claim 36 wherein said label indicates the term of administration is at least six months.

5           43. An article of manufacture of Claim 36 wherein said label indicates the term of administration is at least one year.

10           44. An article of manufacture of Claim 36 wherein said label indicates the term of administration is at least two years.

15           45. An article of manufacture of Claim 36 wherein said label indicates the term of administration is chronic.

          46. An article of manufacture of Claim 36 wherein said compound is the hydrochloride salt thereof.

20           47. An article of manufacture of Claim 36 wherein said human is a post-menopausal female, at no particular risk of developing breast cancer.

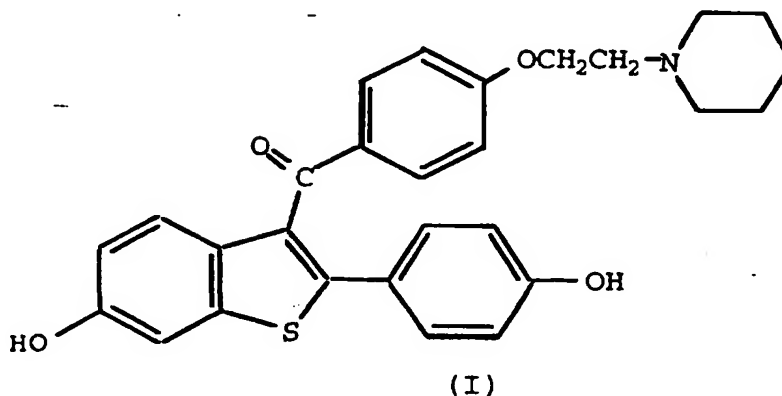
25           48. An article of manufacture of Claim 36 where said breast cancer is *de novo*.

          49. An article of manufacture of Claim 36 wherein said human is a post-menopausal female.

30           50. An article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said packaging material comprises a label which indicates said pharmaceutical agent may be administered, for a  
35           sufficient term and at an effective dose, for preventing

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breast cancer in a post-menopausal human female wherein said pharmaceutical agent is a compound of formula I



5                    or a pharmaceutically acceptable salt or  
solvate thereof.

51. An article of manufacture of Claim 50  
wherein said label indicates an effective dose of the  
10 compound of formula I is between about 30 mg to about 200  
mg/day.

52. An article of manufacture of Claim 50  
wherein said label indicates an effective dose of the  
15 compound of formula I is between about 50 mg to about 150  
mg/day.

53. An article of manufacture of Claim 50  
wherein said label indicates an effective dose of the  
20 compound of formula I is between about 60 mg to about 120  
mg/day.

54. An article of manufacture of Claim 50  
wherein said label indicates an effective dosage of the  
25 compound of formula I is about 60 mg/day.



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55. An article of manufacture of Claim 50 wherein said label indicates the term of administration is at least six months.

5 56. An article of manufacture of Claim 50 wherein said label indicates the term of administration is at least one year.—

10 57. An article of manufacture of Claim 50 wherein said label indicates the term of administration is at least two years.

15 58. An article of manufacture of Claim 50 wherein said label indicates the term of administration is chronic.

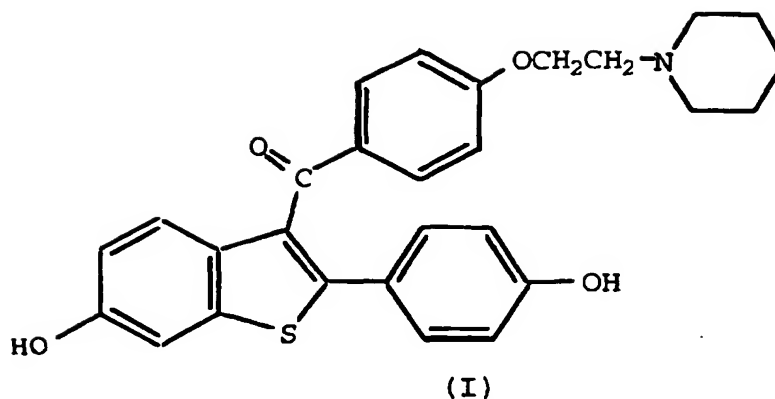
59. An article of manufacture of Claim 50 wherein said compound is the hydrochloride salt thereof.

20 60. An article of manufacture of Claim 50 wherein said post-menopausal female is at no particular risk of developing breast cancer.

25 61. An article of manufacture of Claim 50 where said breast cancer is *de novo*.

30 62. An article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said packaging material comprises a label which indicates said pharmaceutical agent may be administered, for a sufficient term at an effective dose, for preventing breast cancer in a human at no particular risk of developing breast cancer wherein said pharmaceutical agent is a compound of formula I

35



or a pharmaceutically acceptable salt or solvate thereof.

63. An article of manufacture of Claim 62 wherein said label indicates the effective dose of a compound of Formula I is between about 30 mg to about 200 mg/day.

64. An article of manufacture of Claim 62 wherein said label indicates the effective dose of a compound of Formula I is between about 50 mg to about 150 mg/day.

65. An article of manufacture of Claim 62 wherein said label indicates the effective dose of a compound of Formula I is between about 60 mg to about 120 mg/day.

66. An article of manufacture of Claim 62 wherein said label indicates the effective dosage of a compound of Formula I is about 60 mg/day.

67. An article of manufacture of Claim 62 wherein said label indicates the term is at least six months.

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68. An article of manufacture of Claim 62 wherein said label indicates the term is at least one year.

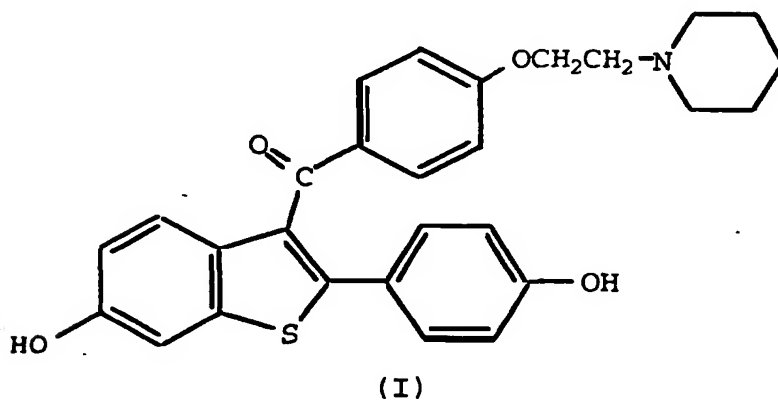
5                    69. An article of manufacture of Claim 62  
                     wherein said label indicates the term is at least two  
                     years.

70. An article of manufacture of Claim 62  
10 wherein said label indicates the term is chronic.

71. An article of manufacture of Claim 62 wherein said compound is the hydrochloride salt thereof.

15           72. An article of manufacture of Claim 62  
wherein said human is a post-menopausal female.

73. The use of a compound of the formula



or a pharmaceutically acceptable salt or solvate thereof, in the preparation of a medicament for preventing breast cancer in a human, said medicament to be administered to said human for a sufficient term and at an effective dose.

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74. The use of Claim 73 wherein said effective dose is between about 30 mg to about 200 mg/day.

5 75. The use of Claim 73 wherein said effective dose is between about 50 mg to about 150 mg/day.

76. The use of Claim 73 wherein said effective dose is between about 60 mg to about 120 mg/day.

10 77. The use of Claim 73 wherein said effective dosage is about 60 mg/day.

78. The use of Claim 73 wherein said term is at least six months.

15 79. The use of Claim 73 wherein said term is at least one year.

20 80. The use of Claim 73 wherein said term is at least two years.

81. The use of Claim 73 wherein said term is chronic.

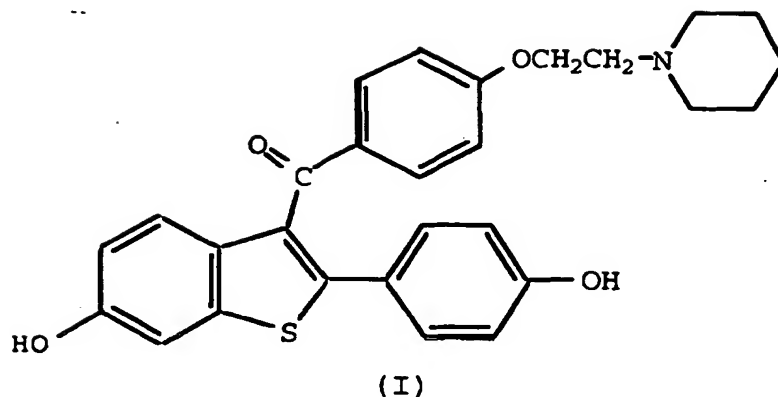
25 82. The use of Claim 73 wherein said compound is the hydrochloride salt thereof.

30 83. The use of Claim 73 wherein said human is a post-menopausal female, at no particular risk of developing breast cancer.

84. The use of Claim 73 where said breast cancer is *de novo*.

35 85. The use of Claim 73 wherein said human is a post-menopausal female.

86. The use of a compound of the formula



or a pharmaceutically acceptable salt or solvate thereof, in the preparation of a medicament for preventing breast cancer in a post-menopausal human female, said medicament to be administered to said post-menopausal human female for a sufficient term and at an effective dose.

87. The use of Claim 86 wherein said effective dose is between about 30 mg to about 200 mg/day.

88. The use of Claim 86 wherein said effective dose is between about 50 mg to about 150 mg/day.

89. The use of Claim 86 wherein said effective dose is between about 60 mg to about 120 mg/day.

90. The use of Claim 86 wherein said effective dosage is about 60 mg/day.

91. The use of Claim 86 wherein said term is at least six months.

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92. The use of Claim 86 wherein said term is at least one year.

5 93. The use of Claim 86 wherein said term is at least two years.

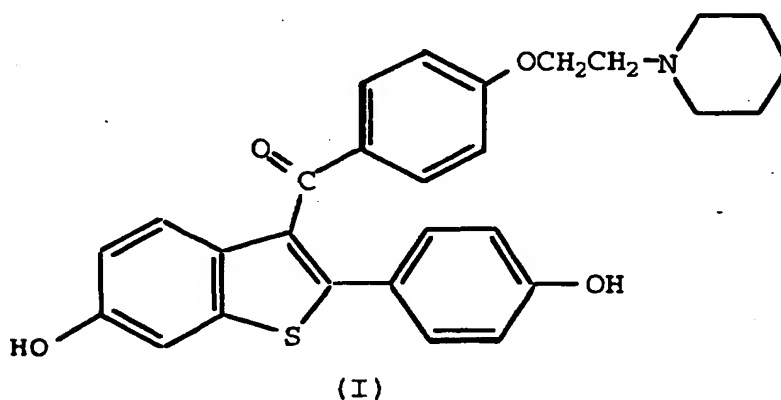
94. The use of Claim 86 wherein said term is chronic.

10 95. The use of Claim 86 wherein said compound is the hydrochloride salt thereof.

15 96. The use of Claim 86 wherein said post-menopausal female is at no particular risk of developing breast cancer.

97. The use of Claim 86 where said breast cancer is *de novo*.

20 98. The use of a compound of formula I



25 or a pharmaceutically acceptable salt or solvate thereof, in the preparation of a medicament for preventing breast cancer in a human being at no particular risk of developing breast cancer, said

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medicament to be administered to said human for a sufficient term and at an effective dose.

5           99. The use of Claim 98 wherein said effective dose is between about 30 mg to about 200 mg/day.

          100. The use of Claim 98 wherein said effective dose is between about 50 mg to about 150 mg/day.

10           101. The use of Claim 98 wherein said effective dose is between about 60 mg to about 120 mg/day.

          102. The use of Claim 98 wherein said effective dosage is about 60 mg/day.

15           103. The use of Claim 98 wherein said term is at least six months.

          104. The use of Claim 98 wherein said term is at least one year.

20           105. The use of Claim 98 wherein said term is at least two years.

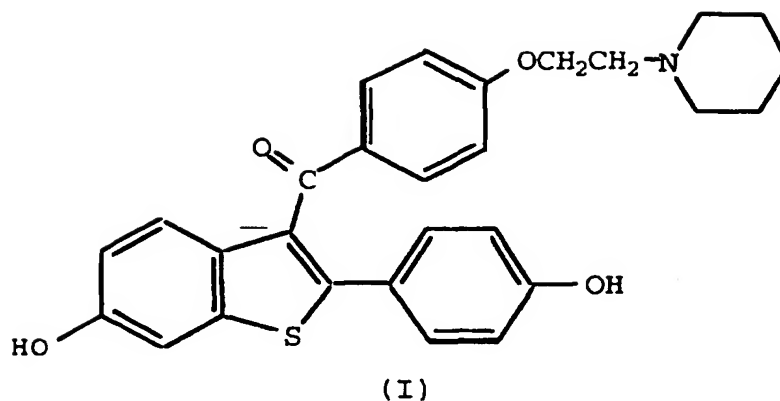
25           106. The use of Claim 98 wherein said term is chronic.

          107. The use of Claim 98 wherein said compound is the hydrochloride salt thereof.

30           108. The use of Claim 98 wherein said human is a post-menopausal female.

35           109. A pharmaceutical formulation comprising as an active ingredient a compound of the formula

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or a pharmaceutically acceptable salt or solvate thereof, said pharmaceutical formulation adapted for preventing breast cancer in a human by administration for a sufficient term an effective dose of said compound to said human.

110. The pharmaceutical formulation of Claim 109 wherein said effective dose is between about 30 mg to about 200 mg/day.

111. The pharmaceutical formulation of Claim 109 wherein said effective dose is between about 50 mg to about 150 mg/day.

112. The pharmaceutical formulation of Claim 109 wherein said effective dose is between about 60 mg to about 120 mg/day.

113. The pharmaceutical formulation of Claim 109 wherein said effective dosage is about 60 mg/day.

114. The pharmaceutical formulation of Claim 109 wherein said term is at least six months.



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115. The pharmaceutical formulation of Claim 109 wherein said term is at least one year.

116. The pharmaceutical formulation of Claim  
5 109 wherein said term is at least two years.

117. The pharmaceutical formulation of Claim 109 wherein said term is chronic.

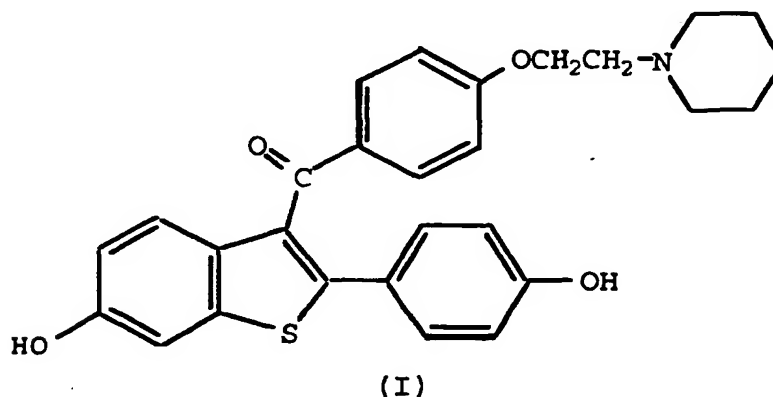
10                    118. The pharmaceutical formulation of Claim  
109 wherein said compound is the hydrochloride salt  
thereof.

119. The pharmaceutical formulation of Claim  
109 wherein said human is a post-menopausal female, at no  
particular risk of developing breast cancer.

120. The pharmaceutical formulation of Claim 109 where said breast cancer is de novo.

121. The pharmaceutical formulation of Claim 109 wherein said human is a post-menopausal female.

122. A pharmaceutical formulation comprising as  
25 an active ingredient a compound of the formula



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or a pharmaceutically acceptable salt or solvate thereof, said pharmaceutical formulation adapted for preventing breast cancer in a post-menopausal human female by administration for a sufficient term an effective dose of said compound to said human.

123. The pharmaceutical formulation of Claim 122 wherein said effective dose is between about 30 mg to about 200 mg/day.

124. The pharmaceutical formulation of Claim 122 wherein said effective dose is between about 50 mg to about 150 mg/day.

125. The pharmaceutical formulation of Claim 122 wherein said effective dose is between about 60 mg to about 120 mg/day.

126. The pharmaceutical formulation of Claim 122 wherein said effective dosage is about 60 mg/day.

127. The pharmaceutical formulation of Claim 122 wherein said term is at least six months.

128. The pharmaceutical formulation of Claim 122 wherein said term is at least one year.

129. The pharmaceutical formulation of Claim 122 wherein said term is at least two years.

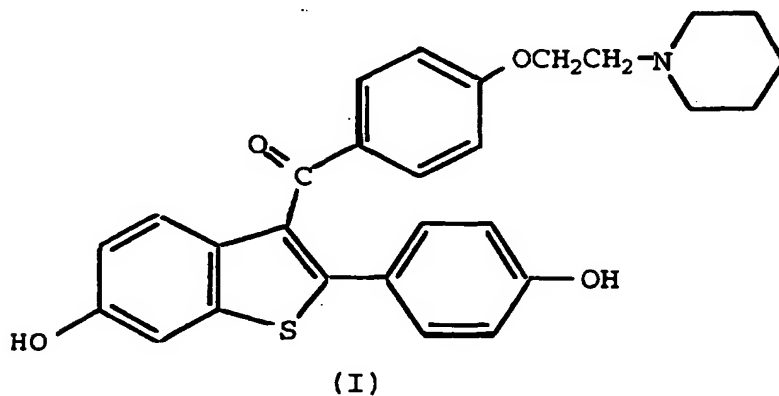
130. The pharmaceutical formulation method of Claim 122 wherein said term is chronic.

131. The pharmaceutical formulation of Claim 122 wherein said compound is the hydrochloride salt thereof.

132. The pharmaceutical formulation of Claim 122 wherein said post-menopausal female is at no particular risk of developing breast cancer.

133. The pharmaceutical formulation of Claim 122 where said breast cancer is de novo.

134. A pharmaceutical formulation comprising  
as an active ingredient a compound of formula I



or a pharmaceutically acceptable salt or solvate thereof, said pharmaceutical formulation adapted to prevent breast cancer in a human being at no particular risk of developing breast cancer, by administration for a sufficient term an effective dose of said compound to said human.

135. The pharmaceutical formulation of Claim 134 wherein said effective dose is between about 30 mg to about 200 mg/day.

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136. The pharmaceutical formulation of Claim 134 wherein said effective dose is between about 50 mg to about 150 mg/day.

5           137. The pharmaceutical formulation of Claim 134 wherein said effective dose is between about 60 mg to about 120 mg/day.

10           138. The pharmaceutical formulation of Claim 134 wherein said effective dosage is about 60 mg/day.

139. The pharmaceutical formulation of Claim 134 wherein said term is at least six months.

15           140. The pharmaceutical formulation of Claim 134 wherein said term is at least one year.

20           141. The pharmaceutical formulation of Claim 134 wherein said term is at least two years.

142. The pharmaceutical formulation of Claim 134 wherein said term is chronic.

25           143. The pharmaceutical formulation of Claim 134 wherein said compound is the hydrochloride salt thereof.

30           144. The pharmaceutical formulation of Claim 134 wherein said human is a post-menopausal female.